United States Food and Drug Administration
Center for Tobacco Products
Potential Tobacco Product Violations Reporting Form
OMB Control No. 0910-0716

SUPPORTING STATEMENT PART A

Terms of Clearance: None.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) programs. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA authority to monitor compliance with Federal tobacco laws and regulations and take corrective action when violations occur.

As part of its enforcement strategy, FDA accepts information from the public regarding potential tobacco product violations of the FD&C Act.

Potential tobacco product violations include, but are not limited to: sales to underage purchasers (persons under 21); flavored cigarette sales; illegal marketing and advertising; distribution of free samples of tobacco products except in limited circumstances; placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas); the manufacture or sale of unauthorized tobacco products; and the sale of cigarettes in packages of less than 20.

FDA currently provides a form that may be used to collect this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report). The public and interested stakeholders can report possible tobacco product violations of the FD&C Act by submitting information on Form FDA 3779 online, via email or postal mail, or by calling FDA's Tobacco Call Center. Instructions on how to report possible tobacco product violations of the FD&C Act can be found at www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.

We therefore request extension of OMB approval of information collection provisions as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The Potential Tobacco Product Violations Report, Form FDA 3779, asks for the following information:

- Date and State where the potential violation occurred;
- Product type (e.g., cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco);
- Tobacco brand;
- Potential violation type;
- Type of potentially violative promotional materials;

- Who potentially violated;
- Name and address of the potential violator (if known);
- Potential violator's website or internet address URL (if available);
- Description of the potential violation;
- Optional filer contact information if additional information is needed or to receive notification the complaint was received; and
- Any additional files or information pertinent to the potential violation.

The information collected will assist FDA in its investigation of violative firms. Respondents to this information collection are members of the public and interested stakeholders.

3. Use of Improved Information Technology and Burden Reduction

Information on reported violations may currently be provided to FDA by using Form FDA 3779 online, via the Tobacco Call Center (toll-free telephone number), email, or by postal mail. Instructions on how to report possible tobacco product violations of the FD&C Act can be found at www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation. It is expected that 99 percent of the users of this program will submit their information electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

This information may be submitted by the public or interested stakeholders. As such, the information collection is not expected to fall disproportionately on small businesses.

6. Consequences of Collecting the Information Less Frequently

FDA will be hindered in its enforcement efforts without the ability to collect information on potential tobacco product violations of the FD&C Act. FDA continues to build its staff, resources, and State/local partnerships needed to enforce the tobacco product provisions of the FD&C Act. Therefore, the assistance of the public and interested stakeholders in reporting potential violations is an important piece of FDA's enforcement strategy.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This section is not applicable.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of June 23, 2026 (91 FR 37410). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of information submitted under section 901 of the FD&C Act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions.

CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA's web and privacy policies are provided on all FDA internet (FDA.gov) pages and the Privacy Impact Assessment (PIA) provides further notice.[1] The Center for Tobacco Products (CTP) Electronic Submissions system (eSub) is a suite of database-supported applications that facilitates the collection, logging, tracking, and retrieval of documents provided to the FDA by the tobacco industry and others (e.g., adverse experience reports from the general public). CTP uses this data to evaluate tobacco products, develop policy, and assess industry compliance with the Family Smoking Prevention and Tobacco Control Act. CTP received HHS approval on the PIA for the Electronic Submissions system and was assigned PIA ID: 2060831.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the number of respondents based on current reporting experience.

FDA estimates the burden for this information collection as follows:

12a. Annualized Hour Burden Estimate

In the burden hour table below, we calculate a total of 3,000 respondents.

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response in Hours	Total Hours
Form FDA 3779; Reporting potential tobacco product violations of the FD&C Act	3,000	2	6,000	0.25 (15 minutes)	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] https://www.fda.gov/about-fda/about-website/website-policies#privacy

Reporting Burden

FDA estimates that submitting the information (online, telephone, email or mail) will take an average of 0.25 hours (i.e., 15 minutes) per response. This estimate is based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Report Form in the past.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports by online form, telephone, email or mail. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,500 hours (3,000 respondents x 2 responses per respondent x 0.25 hours per response).

12b. Annualized Cost Burden Estimate

FDA estimates the cost burden of this collection of information as follows.

Estimated Annual Reporting Cost			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting potential tobacco product violations of the FD&C Act	1,500	$49.02	$ 73,530
	Annual Responses	Cost of USPS Stamp	
Mailing Cost	60	$0.82	$49.20
		Total	$73,579.20

Because the Tobacco Call Center has a toll-free telephone number and an online form, FDA estimates that there is minimal cost for the public and interested stakeholders to report a violation. Referencing 2025 Bureau of Labor Statistics national occupational employment and wage statistics, FDA estimates an average wage for the general public using the "All Occupations (00-0000)" median wage of $24.51 per hour, located at https://data.bls.gov/oes/#/industry/000000. We double this to account for benefits and overhead, yielding an hourly wage rate of $49.02.

Additional costs associated with this collection pertain to the postage cost for mailing a letter containing the reported violation information. FDA estimates the total cost to submit a report via mail to be $49.20. This estimate is based upon 60 responses (1 percent of 6,000 total responses) being submitted via U.S. first-class mail and the cost of a first-class postage stamp at $0.82.

Therefore, the total cost to respondents is estimated to be $73,579.20.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this collection of information is $238,970. This estimate reflects the cost of one (1) full-time equivalent (FTE) employee to process violation reports. Using 2026 GS-12, Step 6, salary and wage data for the Washington DC, DC, metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/html/DCB.aspx and doubling the salary to account for benefits and overhead, we estimate the total cost to the Federal Government to be $238,970 (119,485 x 2).

15. Explanation for Program Changes or Adjustments

There are no changes to the currently approved annual burden hours or annual responses associated with this information collection. The updates reflected in this renewal are limited to revisions to respondent wage rates, postage costs, and Federal Government cost estimates.

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (+/-)	Rationale for Change
Reporting potential tobacco product violations of the FD&C Act	1,500	1,500	0	No change to the approved burden estimate. Updates are limited to respondent wage rates, postage costs, and Federal Government cost estimates.
TOTAL	1,500	1,500	0	

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.